

UNITED STATES FOOD & DRUG ADMINISTRATION

General Licensing Provisions:
Biologics License Application, Changes to an Approved Application,
Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Cooperative
Manufacturing Arrangements

OMB Control No. 0910-0338

No Material or Non-Substantive Change to a Currently Approved Collection (83C):

This change request seeks to include Food and Drug Administration (FDA, the agency) guidance into a currently approved information collection for efficiency of agency operations. The referenced information collection supports implementation of section 351 of the Public Health Service Act (42 U.S.C. 262) and related FDA regulations pertaining to licensed biologics applications (BLAs). A manufacturer of a biological product must demonstrate responsibility for the manufacturing process as described in its BLA (21 CFR 600.3(t)). We developed the guidance document entitled, “*Cooperative Manufacturing Arrangements for Licensed Biologics*,” to assist respondents with various alternative arrangements we have accepted involving more than one manufacturer. The guidance document addresses types of manufacturing arrangements (i.e., short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements) and describes certain reporting and recordkeeping responsibilities associated with these arrangements. The guidance document was issued in November 2008 consistent with regulations in 21 CFR part 601.29 (biologics licensing; guidance documents), as well as our good guidance practice regulations in 21 CFR 10.115 which provide for public comment at any time. Although we believe that the information collection attendant to the recommendations in the guidance are those that would be usual and customary, we provide for 1 burden hour and 1 annual response to account for such activity and have adjusted our estimate accordingly. Upon approval of the change request we intend to discontinue OMB control no. 0910-0629.

In addition, we have removed the cost information inadvertently included to appear at www.reginfo.gov. In our last renewal of the information collection we inadvertently uploaded this information when it already appears at 12b. of our supporting statement.

Submitted: August 2020